ARENA
APPLIED RESEARCH ETHICS NATIONAL ASSOCIATION

132 Boylston Street, 4th Floor
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March 2, 2001

National Human Research Protection
Advisory Committee (NHRPAC)
Attention: Dr. Greg Koski
6100 Executive Boulevard, Suite 3B01
MSC-7507
Rockville, Maryland 20892-7507

Dear Dr. Koski:

Thank you for giving the Applied Research Ethics National Association (ARENA) the opportunity to comment on the document labeled "Draft Interim Guidance," entitled "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subjects Protection" (referred to in this comment letter as "guidance"). We appreciate the initial efforts of the Office of Human Research Protection (OHRP) to address issues of potential financial conflicts of interest in human research.

As you know, ARENA is a subsidiary of Public Responsibility in Medicine and Research (PRIM&R), a nonprofit organization dedicated to promoting the ethical conduct of research. ARENA is a professional association with over 1,200 members who are administrators, chairs, and members of Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs) throughout the United States. ARENA's mission is to support those professionals whose responsibilities include the protection of human and animal research subjects.

The Association of American Universities (AAU), the Council on Governmental Relations (COGR), and the National Association of State Universities and Land-Grant Colleges (NASULGC) have submitted to your office general, substantive, and procedural concerns and recommendations. ARENA concurs with these concerns.

We have summarized our concerns below, realizing that this is a first step in what we anticipate to be an ongoing dialogue. Please note, however, we do recommend withdrawal of the interim guidelines because of an apprehension that the guidelines will prematurely be implemented as policy.

- Currently, there is no clear-cut regulatory mandate in the Federal Policy (i.e., Common Rule), 45 CFR Part 46, 21 CFR Parts 50 and 56 to support the prescriptive nature of the proposed guidance.

- Currently, there is no consensus among the general public, institutions, investigators, and IRBs regarding the appropriate role of IRBs in addressing potential financial conflicts of interest. In ARENA's opinion, expansion of the IRB role to the extent proposed in the guidance may not be the most appropriate or effective means by which to address these concerns. In the current regulatory environment, IRBs are increasingly held accountable for implementing "new" complex responsibilities which might be more appropriately shared. We commend OHRP for drawing attention to the relationship between the IRB and existing conflict of interest mechanisms. However, before issuing even "guidance" in this area, underlying ethical issues should be further analyzed, the extent to which potential financial conflicts of interests impact the rights and welfare of human subjects should be assessed, and the relationship between the existing IRBs and conflict of interest processes should be explored.

- The guidance appears to assume that there are existing financial conflict of interest processes, which are housed within the same institution as the IRB. These assumptions are not reflective of the current environment, in which many clinical trials are conducted outside of an institutional setting.

- There have been no regulations as yet promulgated in the area of institutional conflicts of interest. The AAU and the Association of American Medical Colleges (AAMC) are in the process of assessing the complex and confusing issues that surround institutional financial conflicts of interest. They are committed to developing principles to guide the research community, and we think it would be preferable to await the outcome of those deliberations prior to issuing final guidance.

- There is no consensus among the general public, institutions, investigators, and IRBs regarding the extent to which financial disclosures should be a part of the research protocol and informed consent. ARENA would agree that IRBs and investigators need to consider what financial information should be included in informed consents. However, the suggestions included in the guidance as written are too prescriptive. Specifically, serious consideration should be given to the type of information relayed to participants by way of the consent document.

- From a procedural perspective, ARENA is concerned about the Department of Health and Human Services process for promulgating regulations, policy, and guidance. Our past experience suggests that, no matter what the document is termed (i.e., "regulation," "policy," or "guidance"), regulatory agencies apply the "guidance" as though it had the weight of regulation. We acknowledge OHRP's assurance that this guidance was not intended to be regulation. However, ARENA is concerned that the procedure for issuing the guidance is problematic given the prescriptive tone, the potential impact on regulatory burden, and the lack of consensus. There is a process for review and comment of Executive Branch rulemaking, which was established by the Administrative Procedures Act. The responsibilities outlined in the OHRP guidance are too extensive to be distributed via a Web site, even under the heading "Draft Interim Guidance."

We appreciate this opportunity to comment on the Draft Interim Guidance. Your consideration of our comments and concerns is greatly appreciated.

Sincerely,

Ada Sue Selwitz
ARENA, Public Policy Committee Co-Chair

Gary Chadwick
ARENA, Public Policy Committee

Elizabeth Bankert
ARENA, President

cc: ARENA Public Policy Drafting Committee
ARENA Council
PRIM&R